

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 COME-00 TRSE-00 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/NE:JPSHUMATE(INFO)

-----312201Z 011811 /62

P 312117Z MAY 77
FM SECSTATE WASHDC
TO AMCONSUL HAMILTON PRIORITY

UNCLAS STATE 125133

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BD

SUBJECT: FDA ADVISORY - SALMONELLA CONTAMINATION OF
SPECIAL DIETARY FOOD PRODUCTS (EXTENSION OF RECALL F-049/
050-7)

1. FDA ADVISES THAT THE FOLLOWING PRODUCTS ARE BEING RE-
CALLED:

RECALL NO. F-049-7: "MDC 212-1910-22 PRECISION ISOTONIC
DIET NUTRITIONALLY BALANCED ISOTONIC FORMULA. FOR ORAL OR
TUBE FEEDING. VANILLA ARTIFICIAL FLAVOR. THE DOYLE PHARM-
ACEUTICAL CO., MINNEAPOLIS, MINN., 55416. NET WEIGHT 2.06
OZ. (58.4G)". EXTENDED TO ALL LOTS.

RECALL NO. F-050-7: PRECISION MODERATE NITROGEN DIET. NUT-
RITIONALLY COMPLETE LOW-RESIDUE FOOD. FOR ORAL OR TUBE
FEEDING. VANILLA AND CITRUS ARTIFICIAL FLAVORS. THE DOYLE
PHARMACEUTICAL CO., MINNEAPOLIS, MINN., 55416. NET WEIGHT
2.75 OZ. (78G).

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THESE PRODUCTS ARE INTENDED FOR FEEDING HOSPITAL PATIENTS.

PRODUCT IDENTIFICATION: ALL LOTS OF BOTH PRODUCTS ARE
BEING RECALLED. ALL NEW PRODUCTION TO FOLLOW RECALL WILL
INCLUDE A "Z" TO DESIGNATE IT FROM THE RECALLED PRODUCT.

MANUFACTURER/RECALLING FIRM: THE DOYLE PHARMACEUTICAL CO.,
DIVISION OF DELMARK COMPANY, 5320 WEST 23RD STREET, MINN-
EAPOLIS, MINNESOTA 55416.

2. REASON FOR RECALL: 6 CASES OF SALMONELLOSIS WERE CON-
FIRMED IN INFANTS IN SAN DIEGO, CALIFORNIA BETWEEN OCTOBER
1976 AND JANUARY 1977. FOUR OF THESE CASES WERE RELATED TO
THE USE OF THIS PRODUCT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED PRODUCT RECALL LETTER ISSUED
BY DOYLE PHARMACEUTICAL COMPANY DATED MARCH 7, 1977. LETTER
INDICATES THAT RECIPIENTS ARE TO DETERMINE IF THEY HAVE ANY
OF THE SUSPECT LOTS AND IF SO THEY ARE TO DISCONTINUE DIS-
PENSING THESE LOTS AND RETURN MARKED "ATTENTION: RETURNED
GOODS". THEY ARE ALSO REQUESTED TO NOTIFY ANY PATIENT WHO
HAS BEEN USING PRODUCT IN THEIR HOME. ANY QUESTIONS WITH
RESPECT TO RECALLED PRODUCT SHOULD BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

BVH LTD, HAMILTON, BERMUDA
BERMUDE GENERAL AGENCY
BOX 506, HAMILTON, BERMUDA

BERMUDA PHARMACY LTD.
P O BOX 321, HAMILTON 5
BERMUDA

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BERMUDA DRUG, HAMILTON, BERMUDA
HAMPHARM DISTRIBUTORS, BOX 250
HAMILTON, BERMUDA

KING EDWARD VIII HOSPITAL, HAMILTON, BERMUDA

PURVIS LTD., P O BOX 461, HAMILTON 5, BERMUDA CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD CONTAMINATION, FOODS
Control Number: n/a
Copy: SINGLE
Sent Date: 31-May-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE125133
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770193-0804
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977051/aaaaaawl.tel
Line Count: 104
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: ae27c486-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 22-Mar-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2313540
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - SALMONELLA CONTAMINATION OF SPECIAL DIETARY FOOD PRODUCTS (EXTENSION OF RECALL F-049/ 050-7)
TAGS: OGEN, ETRD, EIND, TBIO, SWEL, BD, FDA
To: HAMILTON
Type: TE
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Review Markings:
Margaret P. Grafeld
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